

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 2 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS**Remarks**

The Office Action mailed May 19, 2005 has been received and reviewed. The pending claims are claims 1-15. Claims 9-12 being withdrawn from examination, as drawn to non-elected inventions, the claims currently under examination are claims 1-8 and 13-15. Reconsideration and withdrawal of the rejections are respectfully requested.

The 35 U.S.C. §103 Rejection of claims 1-6 over Wilson in view of Olsvik and Sun

The Examiner maintained the rejection of claims 1-6 under 35 U.S.C. §103 as being unpatentable over Wilson (U.S. Patent No. 5,985,596) in view of Olsvik et al. (*Clin. Microbiol. Rev.*, 1994;7(1):43-54) and Sun et al. (*J. Indust. Microbiol. Biotech.*, 2001; 27(2):126-128). Applicants continue to traverse this rejection and maintain that this rejection of claims 1-6 under 35 U.S.C. §103 as being unpatentable over Wilson in view of Olsvik et al. and Sun et al. is improper. Claims 1-6 are drawn to a "method of detecting a bacterial cell in a sample comprising:

- contacting the sample with bacteriophage comprising a binding agent . . . ;
- incubating the sample under conditions effective for the bacteriophage comprising a binding agent to infect the bacterial cell, and . . . form new bacteriophage and release new bacteriophage into the sample, wherein the new bacteriophage do not comprise a binding agent;
- contacting the sample with a substrate comprising immobilized ligand for the binding agent . . . ;
- removing the complexes of bacteriophage comprising a binding agent and substrate comprising immobilized ligand from the sample; and
- detecting new bacteriophage in the sample from which complexes have been removed."

Applicants respectfully submit that the combined teachings of Wilson in view of Olsvik et al. and Sun et al. do not teach the claimed method. Applicants submit that Wilson in view of Olsvik et al. and Sun et al. do not teach a method that includes all of the steps of the method of

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 3 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS

claims 1-6. In particular, Wilson in view of Olsvik et al. and Sun et al. do not teach a method that includes:

-*contacting* a sample with bacteriophage comprising a binding agent;

-*incubating* the sample under conditions effective for the bacteriophage comprising a binding agent to infect the bacterial cell, . . . form new bacteriophage and release new bacteriophage into the sample, wherein the new bacteriophage do not comprise a binding agent;

-*contacting* the sample with a substrate comprising immobilized ligand for the binding agent . . . ;

-*removing* the complexes of bacteriophage comprising a binding agent and substrate comprising immobilized ligand from the sample; and

-*detecting* new bacteriophage in the sample from which complexes have been removed."

Applicants further submit that Wilson in view of Olsvik et al. and Sun et al. do not teach contacting a sample with *a bacteriophage comprising a binding agent*, and do not teach incubating the sample *under conditions effective for the bacteriophage comprising a binding agent to infect the bacterial cell, . . . form new bacteriophage and release new bacteriophage into the sample, wherein the new bacteriophage do not comprise a binding agent*.

Further, Applicants respectfully submit that the requisite motivation to combine the teachings of Wilson in view of Olsvik et al. and Sun et al. to obtain the claimed invention is lacking. Applicants submit that one of ordinary skill in the art would not be motivated to combine the teachings of Wilson (teaching a method of assaying for a slow growing bacterium by exposing a first bacterium to infection by a phage, inactivating phage particles that have not been absorbed by the first bacterium, cultivating the first bacterium in the presence of a second bacterium, and assessing the extent of plaque formation and/or growth of the second bacterium), the teachings of Olsvik et al. (teaching the direct detection of viral RNA or DNA in a sample by the use of oligonucleotide probes linked to magnetic beads as primers in polymerase chain

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 4 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS

reactions), and the teachings of Sun et al. (teaching the construction of a biosorbent for the capture of bacterial cells within a sample) to obtain the method of claims 1-6.

Applicants continue to submit that the Examiner has engaged in the impermissible hindsight reconstruction of the claimed invention. The Examiner asserted that "any judgement of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such reconstruction is proper" (see page 5 of Office mailed May 19, 2005). Applicants respectfully submit that the Examiner's reasoning is incomplete. As recently reasserted in *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.* (Fed. Cir., No. 04-1493, June 9, 2005), 35 U.S.C. §103 specifically requires an assessment of the claimed invention "as a whole." This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the cited references and combined them in the claimed manner. In other words, 35 U.S.C. §103 requires some suggestion or motivation, before the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998).

This "as a whole" instruction in 35 U.S. §103 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a reference corresponding to each component. This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result - often the essence of invention. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004). Simply identifying the various elements of a claim in the cited references does not render a claim obvious. *Ruiz*, 357 F.3d at 1275. Instead, 35 U.S. §103 requires some suggestion or motivation in the prior art to make the new combination. *Rouffet*, 149 F.3d at 1355-56.

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 5 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS

Applicants submit that the Examiner has engaged in an improper part by part analysis of the claimed method. Applicants submit that the requisite motivation to combine the teachings of Wilson in view of Olsvik et al. and Sun et al. to obtain the claimed invention, as a whole, is lacking.

Finally, Applicants adamantly, yet respectfully, submit that the Examiner is mischaracterizing the teachings of Olsvik et al. The Examiner asserted that "[w]hile . . . the Olsvik reference is primarily concerned with the use of magnetic separation (MS) of nucleic acids, this does not constitute the entirety of the reference's teachings. Rather, the background of the teachings of the reference (c.g. page 43) indicates that it has been shown in the art that MS is useful for the detection of virus particles . . . [and] that, as suggested by Olsvik, MS would also be useful for the detection and separation of phage particles from a sample" (page 4 of Office Action mailed May 19, 2005). Applicants submit that the teachings of Olsvik et al. are limited only to teachings of the use of magnetic separation for the detection of viral nucleic acids in a sample. Olsvik et al. provides no teachings on the use of magnetic separation for the detection of intact phage particles or for the removal of phage particles from a sample. Counter to the Examiner's assertion, Applicants' review of page 43 indicates no teachings for the use of magnetic separation for the detection of intact phage particles or for the removal of phage particles from a sample.

In conclusion, in view of the above discussion, Applicants submit that claims 1-6 are not *prima facie* obvious over Wilson in view of Olsvik et al. and Sun et al. Reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is requested.

The 35 U.S.C. §103 Rejection of claims 7 and 8 further in view of Teodorescu

The Examiner maintained the rejection of claims 7 and 8 as being unpatentable over Wilson, Olsvik et al., and Sun et al., as applied to claims 1-6, and further in view of Teodorescu et al. (U.S. Patent No. 4,797,363). Applicants continue to traverse this rejection and maintain, as previously presented in the Amendment and Response filed March 16, 2005, that the deficiencies

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 6 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS

of Wilson, Olsvik et al., and Sun et al., as applied to claims 1-6, are not corrected by the teachings of Teodorescu et al. Applicants respectfully submit that claims 7 and 8 are not *prima facie* obvious over Wilson in view of Olsvik et al. and Sun et al. as applied to claims 1-6 and further in view of Teodorescu et al. Reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is requested.

The 35 U.S.C. §103 Rejection of claims 13-15 further in view of Yazdankhah

The Examiner maintained the rejection of claims 13-15 as being unpatentable over Wilson, Olsvik et al. and Sun et al., as applied above, and further in view of Yazdankhah et al. (*Vet. Microbiol.*, 1998,62(1):17-26). Applicants traverse this rejection. Applicants continue to maintain, that the deficiencies of Wilson, Olsvik et al., and Sun et al., as applied to claims 1-6 are not corrected by the teachings of Yazdankhah et al.

Further, Applicants continue to maintain, that the requisite motivation to combine the teachings of Wilson in view of Olsvik et al. and Sun et al. and further in view of Yazdankhah et al. is lacking. Applicants submit that one of ordinary skill in the art would not be motivated to combine the teachings of Yazdankhah et al. (teaching a method of detecting *Staphylococcus* bacteria in milk samples by the use of magnetic beads coated with monoclonal antibodies specific to the *Staphylococcus* bacteria) with the teachings of Wilson (teaching a method of assaying for a slow growing bacterium by exposing a first bacterium to infection by a phage, inactivating phage particles that have not been absorbed by the first bacterium, cultivating the first bacterium in the presence of a second bacterium, and assessing the extent of plaque formation and/or growth of the second bacterium), the teachings of Olsvik et al. (teaching the direct detection of viral RNA or DNA in a sample by the use of oligonucleotide probes linked to magnetic beads as primers in polymerase chain reactions), and the teachings of Sun et al. (teaching the construction of a biosorbent for the capture of bacterial cells within a sample) to obtain the method of claims 13-15. In fact, the Examiner acknowledges the "different focus of each of the references" (page 8, Office Action mailed May19, 2005).

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 7 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS

Frankly, Applicants do not understand the Examiner's justification of the motivation to combine the teachings of Wilson in view of Olsvik et al. and Sun et al. and further in view of Yazdankhah et al. presented in the paragraphs bridging pages 8 and 9 of the Office Action mailed May 19, 2005, and continue to submit that the Examiner has engaged in the impermissible hindsight reconstruction of the claimed invention. For example, while the Examiner acknowledges that Yazdankah teaches "the use of MS [magnetic separation] for the detection of bacterial cells" he argues that "because the methods used in these references [Yazdankah, Sun, and Olsvik] are so similar, and because the use of antibodies to detect phage is known in the art, it would be obvious to those in the art that the MS method of Yazdankhah could also be used for the detection of phage" (page 9, Office Action mailed May 19, 2005). Applicants do not understand this assertion. Applicants submit that the methods taught in each of Yazdankah, Sun, and Olsvik are not, as asserted by the Examiner, "so similar." Further, Applicants submit that the Examiner is improperly relying on unsubstantiated and vague assertions of what is well known in the art to substantiate this rejection.

Finally, Applicants continue to maintain, as previously presented in the Amendment and Response filed March 16, 2005, that the teachings of Wilson in view of Olsvik et al. and Sun et al. and further in view of Yazdankhah et al. do not teach each and every element of the method of claims 13-15. In maintaining this rejection, the Examiner asserted that the Applicants' "traversal of this argument is substantially the same as the . . . traversal of the rejection of claims 1-6." Applicants respectfully submit that this is incorrect and assert that the Examiner is failing to read and examine independent claim 13 (and its dependent claims 14 and 15) in its entirety, as distinct from independent claim 1 (and its dependent claims 2-6).

In particular, Applicants submit that the teachings of Wilson in view of Olsvik et al. and Sun et al. and further in view of Yazdankhah et al. do not teach or suggest the method of claim 13-15; a method comprising:

"contacting the sample with a *first substrate* comprising immobilized ligand for the binding agent under conditions effective for a complex to form between the bacteriophage

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 8 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTS

comprising the binding agent and *the first substrate* comprising immobilized ligand for the binding agent;"

"removing the complexes of bacteriophage comprising a binding agent and *first substrate* comprising immobilized ligand from the sample;"

"contacting the sample with *a second substrate* comprising immobilized binding agent specific for the *new bacteriophage*, under conditions effective for a complex to form between the *new bacteriophage* and *the second substrate* comprising immobilized binding agent for the *new bacteriophage*;"

"removing the complexes of *new bacteriophage* and *second substrate* comprising immobilized binding agent for the new bacteriophage;" or

"detecting the complexes of *new bacteriophage* and *second substrate* comprising immobilized binding agent for the new bacteriophage."

Thus, Applicants submit that Wilson in view of Olsvik et al. and Sun et al. and further in view of further in view of Yazdankhah et al. do not teach each and every element of the method of claims 13-15. Claims 13-15 are not *prima facie* obvious over Wilson in view of Olsvik et al. and Sun et al. and further in view of further in view of Yazdankhah et al.

In conclusion, in view of the above discussion, Applicants submit that claims 13-15 are not *prima facie* obvious over Wilson in view of Olsvik et al. and Sun et al. further in view of Yazdankhah et al. Reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a) is requested.

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

Page 9 of 9

Serial No.: 10/685,925

Confirmation No.: 7050

Filed: October 15, 2003

For: ASSAYS TO DETECT OR QUANTIFY BACTERIAL OR VIRAL PATHOGENS AND CONTAMINANTSSummary

It is respectfully submitted that the pending claims 1-15 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
ANDERSON et al.

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

July 19, 2005
Date

NAJ/skd

By: Nancy A. Johnson
Nancy A. Johnson
Reg. No. 47,266
Direct Dial (612) 305-4723

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19th day of July, 2005, at 2:45 pm (Central Time).

By: Sue Dombroske
Name: Sue Dombroske